

553,821

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
4 November 2004 (04.11.2004)

PCT

(10) International Publication Number  
**WO 2004/093780 A2**

(51) International Patent Classification<sup>7</sup>: **A61K**

(21) International Application Number:  
PCT/IN2004/000102

(22) International Filing Date: 16 April 2004 (16.04.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
330/MAS/2003 21 April 2003 (21.04.2003) IN

(71) Applicant (for all designated States except US): **MATRIX LABORATORIES LTD** [IN/IN]; 1-1-151/1, IV Floor, Sairam Towers, Alexander Road, Secunderabad 500 003 (IN).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CHAVA, Satyanarayana** [IN/IN]; Plot No 40, Parkview Enclave, Manovikas Nagar, Hasmathpet Road, Secunderabad 500 009 (IN). **GORANTLA, Seeta, Ramanjaneyulu** [IN/IN]; Plot No-12, Sai Ansh Arcade, Durgavihar Colony, Tirumalgherry, Secunderabad 500 015 (IN). **INDUKURI,**

**Venkata, Sunil, Kumar** [IN/IN]; Flat No-104, Raghavendra Towers, KPHB-VI Phase, Kukatpally, Hyderabad 500 072 (IN).

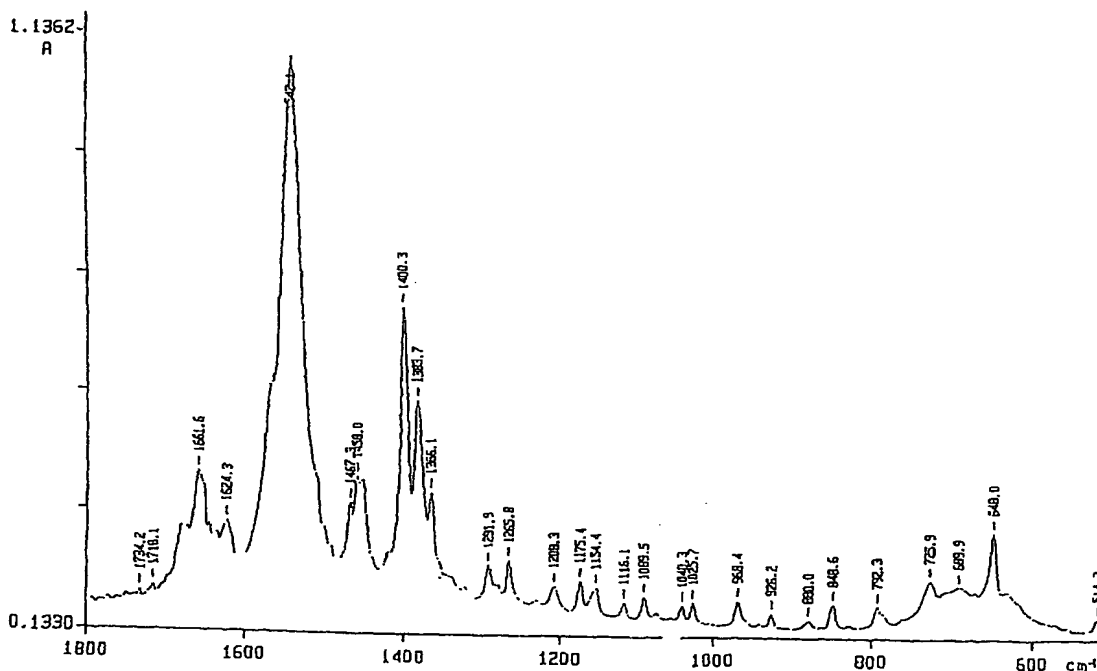
(74) Agent: **CH., V., Ramana, Rao**; Matrix Laboratories Ltd, Plot No. 38, Phase-IV, Ida, Jeedimetla, Hyderabad 500 055 (IN).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR,

[Continued on next page]

(54) Title: PROCESS FOR THE PREPARATION OF GABAPENTIN FORM-II



(57) Abstract: The present invention relates to a new industrial feasible process for the preparation of Gabapentin Form-II via a novel intermediate Gabapentin hemisulphate hemihydrate with out forming Gabapentin Form-III by neutralizing the Gabapentin hemisulphate hemihydrate solution with a base at higher temperatures followed by cooling to yield Gabapentin Form II with sulphate ions less than 100 ppm with respect to Gabapentin.

WO 2004/093780 A2



GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG,

CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designation US
- of inventorship (Rule 4.17(iv)) for US only

**Published:**

- without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.